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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,227	04/13/1999	MICHAEL G. HAYEK	IAM467PA	1823

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/05/2002

3/

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/291,227

Applicant(s)

HAYEK, MICHAEL G.

Examiner

Shengjun Wang

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1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Request for a Continued Examination (RCE) under 37 CFR 1.114 filed on August 19, 2002 based on parent Application No. 09/291227 is acceptable and a RCE has been established. An action on the RCE follows.

Receipt of applicants' remarks and the declaration submitted August 19, 2002 is acknowledged.

Claim Rejections 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (US Patent 5,993,714) in view of Jyonouchi et al. (IDS, March 22, 2002) in view of Anon (IDS, March 22, 2002), and Krinsky (IDS, March 22, 2002), and further in view of CRC Handbook of Toxicology (of record).

Ito et al. teach a animal feed comprising antioxidant selected from carotene and lutein etc. the antioxidant is in the concentration of about 0.02%. Ito further teaches method for improving the health of animal comprising feeding the animal (including dog and cat) with the antioxidant agent. The amount of the antioxidant agents is 0.02 g/kg-body weight. See, particularly, column 5, lines 16-20, and claims 8-14. Ito also teaches that the usefulness of carotenoids as food additive is for a broad range of animals including mammals and fish. See, particularly, column 6, lines 8-11.

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3. Ito et al. does not teach expressly to choose lutein as the active ingredients, or particularly employ the lutein containing feed for immune enhancing purpose.

4. However, Jyonouchi et al teaches that carotenoids in general, and lutein in particular, as antioxidants, are known to be useful in enhancing immune response animals. See the abstract, and the discussion. Anon teaches an ailment specific dietary supplements comprising lutein which may be useful for enhancing immune response. See, the whole article. Krinsky teaches that it is well known that carotenoids have effect of immune enhancement in animals. See the abstract, and the summary. The CRC Handbook of Toxicology, 1995, at page 11 describes the fact that experimental animal models are known to be useful in condition that mimic human disease.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Ito's feed with lutein as the antioxidant, to feed cat or dog for enhancing their immune systems.

5. A person of ordinary skill in the art would have been motivated to employ Ito's feed with lutein as the antioxidant, to feed cat or dog for enhancing their immune systems because lutein is known to be useful for enhancing the immune system of animals, and is known to be useful in dog or cat feed. As to claims 9-11, reciting particular function of the process, note the function limitation in the preamble is generally not accorded any patentable weight where it merely recites the purpose of the process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Response to the Arguments

6. Applicant's amendments, remarks and declaration submitted March 22, 2002 and August 19, 2002 have been fully considered, but are not persuasive in view of the rejection set forth above for reasons discussed below.

7. The declaration under 37 CFR 1.132 filed August 19, 2002 is insufficient to overcome the rejection of claims 1 and 3-11 based upon Ito et al., Jyonouchi et al., Anon, and Krinsky, CRC Handbook of Toxicology as set forth above because: it includes statements which amount to an affirmation that it is not obvious for oral administering lutein to animal, but does not provide objective evidence for supporting the conclusion. In view of Ito's teaching that lutein is used as food additive, oral administration of lutein is obvious.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

8. Regarding the suggestion for employing lutein ⁱⁿ human, See, Jyonouchi et al. the summary; and Krinsky the abstract. Applicants' arguments of the unobviousness for specifically treating dog or cat are unpersuasive for reasons stated in the prior advisory action. Further, Jyonouchi reference suggests that lutein's immune enhancing activity is generally applied to animals, including human. Note that mouse is an old and well-known animal models in biological studies for mammals. The fact is that lutein has been suggested to be useful for enhancing the immune response in mammals, particularly in humans and has been proved to be useful for the enhancement in mouse. It would have been reasonably expected to be useful for the enhancement in dog and cat, considering that mouse is genetically closer to dog and cat than to humans. There is no indication or suggestion in Jyonouchi reference, or any other references,

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that lutein's bioactivity is limited to mice only. If applicants have evidence to believe that dog and cat are distinct from other animal as to the immune response, or the absorption or metabolite of carotenoids, such evidence would be favorably considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

November 1, 2002



RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200